

## **REMARKS**

### **Status of the Claims.**

Claims 1 to 3, 17 to 20, and 25, 26, 28 and 29 are as originally presented.

Claims 4 to 9, 11, 12, 15, 16, 27 and 43 to 48 are currently amended. Support for amendments to claims 4, 5, 43 and 44 can be found at least at page 4, lines 4 to 15; at page 27, line 22 to page 29, line 27; and in common general knowledge in the art. Claim 6 has been amended to improve the overall clarity of the claim. Support for amendments to claims 7 to 9, 46 and 47 can be found at least at page 27, line 22 to page 29, line 27; at page 30, lines 17 to 31 and in original claims 7 to 9, 46 and 47. Claims 15, 16 and 27 have been amended to correct an obvious typographical error.

Claims 10, 13, 14, 21 to 24, 30 to 42 and 49 to 57 have been canceled without prejudice or disclaimer.

New claims 87 to 96 have been added. Support for new claims 87 to 96 can be found at least at page 42, lines 11 to 28 and in Figures 3A to 3E and 4 of the specification as filed.

By this Amendment, no new matter has been added to the application.

### **Response to First Restriction Requirement**

The Examiner issues a first restriction requirement under 35 U.S.C. § 121 between the following subject matter:

- I. “Claims 1 to 29 and 43 to 53 drawn to a method of altering an insulin-associated parameter in a subject comprising administering to said subject a ghrelin or analog thereof; and an unacylated ghrelin or analog thereof”; and
- II. “Claims 30 to 42 and 54 to 57, drawn to a composition comprising a ghrelin or analog thereof, and a kit comprising the same.”

In response to this first restriction requirement, Applicants hereby elect the subject matter identified by the Examiner in Group I drawn to a "method of altering an insulin-associated parameter in a subject comprising administering to said subject a ghrelin or analog thereof, and an unacylated ghrelin or analog thereof", now subsisting in claims 1 to 9, 11, 12, 15 to 20, 25 to 29, 43 to 48 and 87 to 96.

In accordance with this election, Applicants reserve all rights in the non-elected claims, including the right to file one or more divisional applications covering the subject matter thereof.

The election of invention Group I is made **without traverse**.

#### **Response to Second Restriction Requirement**

The Examiner issues a second restriction requirement under 35 U.S.C. § 121 and 371 between the following subject matter:

"Claims 17 to 24 and 33 to 39 are drawn to a number of ghrelin or unacylated ghrelin. Each ghrelin peptide (SEQ ID NO: 1 or 3) and each unacylated ghrelin (SEQ ID NO: 2 or 4) of Group I or II are drawn to a patentably distinct amino acid sequence...Therefore, applicant must choose a single sequence of ghrelin (e.g., SEQ ID NO: 1) and a single sequence of unacylated sequence (e.g., SEQ ID NO: 4) against which the search should be performed."

In response to this second restriction requirement, Applicants hereby elect the ghrelin amino acid sequence as set forth in SEQ ID NO: 1 and the unacylated ghrelin sequence as set forth in SEQ ID NO: 2, now subsisting in claims 17, 18, 19 and 20.

In accordance with this election, Applicants reserve all rights in the non-elected claims, including the right to file one or more divisional applications covering the subject matter thereof.

The election of invention Group I is made **with traverse**.

Applicants submit that the difference between the amino acid sequences depicted in SEQ ID NOs: 1 and 3 and the amino acid sequences depicted in SEQ ID NO: 2 and 4 (see, for example,

at least at page 11, lines 24 to 28 and at page 12, lines 1 to 4 of the specification as filed) is such that it should not create an undue burden on the Examiner's search since the primary amino acid sequence is highly similar. Reconsideration and withdrawal of the Examiner's second restriction requirement are respectfully requested.

### **Response to Species Election**

The Examiner issues a requirement under 35 U.S.C. § 121 as the Examiner is of the view that certain claims are directed to patentably distinct species. More specifically, the Examiner alleges that:

“Insulin-associated parameter: Claims 4-5 and 43-44 are drawn to a number of patentably distinct species (insulin-associated parameters), e.g., insulin level, insulin resistance, free fatty acid level, insulin activity, insulin sensitivity.”

In response to this species election requirement, Applicants elect species “insulin level” as an insulin-associated parameter. The elected species “insulin level” subsists in amended claims 4, 5, 43 and 44.

In accordance with this election, Applicants reserve all rights in the non-elected species, including the right to file one or more divisional applications covering the subject matter thereof.

The election of species “insulin level” is made **with traverse**.

Applicants submit that the insulin-associated parameters specified in claims 4, 5, 43 and 44 should be considered together. These parameters, when considered in the context of insulin metabolism, are related in structure and function. Therefore, examination of these species would not increase the burden upon the Examiner's search. Reconsideration and withdrawal of the Examiner's species election are respectfully requested.

The Examiner issues a further requirement under 35 U.S.C. § 121 as the Examiner is of the view that certain claims are directed to patentably distinct species. More specifically, the Examiner alleges that:

“Insulin-resistance condition: Claims 8-10 and 47-49 are drawn to a number of patentably distinct species (insulin-resistance state or condition), e.g., postprandial state, reduced growth hormone level, reduced growth hormone activity, obesity, diabetes, intravenous nutrition due to critical illness, metabolic syndrome X, pituitary gland deficiency, intravenous nutrition.”

In response, to this species election requirement, Applicants elect species “obesity” as an insulin resistance condition. The elected species “obesity” subsists in amended claims 8, 9, 47 and 48.

In accordance with this election, Applicants reserve all rights in the non-elected species, including the right to file one or more divisional applications covering the subject matter thereof.

The election of species “obesity” is made **with traverse**.

Applicants submit that the insulin conditions specified in claims 8, 9, 47 and 48 should be considered together. These conditions, when considered in the context of insulin resistance, are related in structure and in function. Therefore, examination of these species would not increase the burden upon the Examiner’s search. Reconsideration and withdrawal of the Examiner’s species election are respectfully requested.

**CONCLUSION**

Applicants hereby petition for a one month extension of time to file this response. Please charge the \$130 fee for the one month extension to our Deposit Account No. 08-0219. In the event other fees are due, please charge any underpayments or credit any overpayments to our Deposit Account No. 08-0219, under Order No. 0290494.00122US1, from which the undersigned is authorized to draw.

This application is believed to be in condition for allowance. A prompt and favorable action on the merits of the application is earnestly solicited.

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Respectfully submitted,

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